Aventis Pasteur

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COMMITTEE AND HELP COMMITTEE
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REGARDING PROJECT BIOSHIELD

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Mr. Chairman and Members of the Committee, it is an honor for me to testify before you today regarding Project BioShield and its likely impact in bringing private sector talent and investment into our nation's bio-defense effort.

I appear before you today representing one company – Aventis Pasteur. Aventis Pasteur is the largest company in the world devoted entirely to vaccine research, development, and manufacturing. Aventis Pasteur produces approximately 1.4 billion doses of vaccines annually, making it possible to protect 500 million people across the globe. The company offers the broadest range of vaccines, providing protection against 20 bacterial and viral diseases.

The company manufactures influenza vaccine and several other vaccines at its United States headquarters in Swiftwater, Pennsylvania. Over the years, Aventis Pasteur has had enormous successes, including the first application of conjugate vaccine technology and the licensing of the first infant acellular pertussis vaccine. While being involved in vaccine development, Aventis Pasteur also routinely supplies vaccines and biologicals needed by both civilian and military populations, including vaccines against tetanus and diphtheria, yellow fever, Japanese encephalitis, meningitis, typhoid fever, and influenza to name a few.

Aventis Pasteur has partnered with the Federal government in times of peace as well as in times of conflict. Immediately following the attacks on the World Trade Center on September 11, 2001, Aventis Pasteur worked closely with metropolitan New York and New Jersey public health and city officials to donate 50,000 doses of Tetanus Diphtheria Toxoids Adsorbed vaccine to the relief efforts. Most recently in 2002, Aventis Pasteur demonstrated this commitment by donating approximately 85 million doses of smallpox vaccine to the Federal government's emergency preparedness stockpiles. The company has always supplied the United States military with needed vaccines, including those being used today by our troops fighting in Iraq. The company has responded to more than one Federal request for proposal for bio-defense measures, and therefore, has current experience on this subject. Finally, Aventis Pasteur has been a leading participant in the Global Polio Eradication Initiative, a partnership created to deliver polio vaccine to every child under five, worldwide. Aventis Pasteur has donated a total of 120 million vaccine doses since 1997 under this initiative.

Aventis Pasteur supports the objectives of Project BioShield to expedite the Federal government's ability to contract for needed bio-defense products and to provide important certainty to applicants that money will be available to meet contractual commitments over a period of years. Development and production of complex medical and biological products requires a number of years under the most favorable circumstances and multi-year contracting needs to be available. Passage of this legislation was a significant step forward in preparing the Nation to meet the challenge of defending against bio-terror.

While we recognize that the legislation includes significant positive steps toward developing the nation's bio-defense capabilities, Congress must ensure that Project Bioshield is properly implemented by the Department of Health and Human Services (HHS). Moreover, Congress can significantly improve the law in the area of liability protection and contracting reform by amending the law as part of Project Bioshield II. These changes will dramatically strengthen Project BioShield and help ensure that its most important objective -- to ensure the efficient development of needed safe and effective bio-defense products -- is achieved.

HHS must ensure that key provisions of Project Bioshield are implemented to their Fullest

During the Congressional debate on Project Bioshield, Aventis Pasteur strongly supported the need to provide for the possibility of the Federal government entering into agreements (including contracts, grants, cooperative agreements, and "other transactions") that permit the HHS Secretary to contract with bio-defense companies for research and development and manufacturing/production under one agreement. Reports supporting the House version of Project Bioshield issued by all three Committees of jurisdiction makes clear this was the unquestionable and worthy intent of Congress.

A company like Aventis Pasteur, which not only does research and development, but emphasizes the reliable manufacture of millions of doses of vaccines, needs the certainty that satisfactory completion of research and development will lead to a manufacturing agreement. HHS must take the steps necessary to ensure that Congressional intent is fully realized as it manages the regulatory process.

Similarly, Project Bioshield provides HHS with broad steamlined procurement authorities to ensure that the contract process is expedited with as little burden to commercial contractors as possible. This includes significantly reducing the burdens on prospective contractors by limiting the applicability of certain procurement regulations to eliminate the need to alter their commercial business practices significantly in order to produce bio-defense countermeasures for the Federal government. In accordance with Congressional intent, HHS must ensure that Project Bioshield is implemented to ensure the "Request for Proposal" process makes maximum use of these streamline authorities.

The need for Project Bioshield II

Project Bioshield was a significant step in the right direction. Congress and the Administration should be commended for their leadership; however, several issues must be addressed in BioShield II to enable the vaccine industry to more effectively and efficiently develop safe and effective bio-defense countermeasures. Passage of Project Bioshield II, which should address these issues, would send a significant signal that the Federal government is, indeed, serious about ensuring the nation is protected.

Bioshield II should expressly provide for the authority limit the extent of liability for any contractor engaging in research, development, and production of BioDefense countermeasures

The issue of potential liability for any entity that provides, or performs research and development related to, bio-defense countermeasures absolutely must be addressed in order to stimulate private sector interest in entering into agreements for such countermeasures. For example, the absence of liability protection was a major obstacle in the recent procurement by NIH for development of the next-generation of Anthrax vaccine and continues to be a major hurdle for our company. We would try to obtain commercial insurance, but the practical reality today is that it is unlikely to be available for projects of this nature. Project Bioshield is silent with respect to addressing liability.

The passage of the Homeland Security Act of 2002 radically altered the way the United States will go about promoting the development of technologies designed to counter against a terrorist attack. This was accomplished by means of the SAFETY Act (which stands for the "Support Anti-Terrorism by Fostering Effective Technology."). Under the SAFETY Act, a wide array of legal protections are now available to qualified sellers, vendors, subcontractors, and buyers of anti-terror technology products and services, including bio-defense countermeasures. Such protections take the form of drastically reduced liability in the event an anti-terror technology fails and damages or casualties result.

Products and services that are developed following an act of terrorism might also be considered to be deployed in defense against, in response to, or recovery from an act of terrorism and thus be eligible to receive the protections of the SAFETY Act. In the context of pharmaceutical products, this would encompass giving SAFETY Act coverage to vaccines or drugs that were designed to counter a biological agent that was previously used in a terror attack. Indeed, we have been advised by counsel that there is a very strong argument to be made that pharmaceutical products manufactured in part as a response to the 2001 anthrax attacks are eligible for SAFETY Act protection. Providing SAFETY Act coverage to pharmaceutical products currently being manufactured is in line with the purposes and the text of the SAFETY Act, as it was explicitly written to provide protection for technology and services deployed in "response" to an act of terrorism.

In response to the 2001 anthrax attacks, a number of pharmaceutical products are being prepared and deployed in order to reduce the vulnerability of the United States to another anthrax attack. Since those products are in "response" to an act of terrorism, there should be no doubt that they are eligible for SAFETY Act protections, and extending coverage to them is in line with the intent of the SAFETY Act. For instance DHS has explicitly stated that the success of the SAFETY Act depends "upon encouraging Sellers to develop new and innovative technologies to respond to the ever-changing threats to the American people." 68 Fed. Reg. 59,692 (2003). It would be in line with that directive then to extend protections to pharmaceutical products that are developed and deployed specifically to respond to the threat demonstrated by a terrorist attack that previously occurred.

Recognizing that the protections of the SAFETY Act already extend to pharmaceutical products is an important step in fostering homeland security. More, pharmaceutical products that are developed and manufactured after an act of terrorism has occurred should also be eligible for protection under the SAFETY Act. The perfect example there would be vaccines and drugs developed, manufactured and deployed in the wake of the 2001 anthrax attacks. Such products should be eligible for SAFETY Act protection as they are being deployed in response to an event that represents a triggering act of terrorism. That position is logical in light of the liability risks faced by pharmaceutical companies as well as the risks faced by the United States as a whole if it is unprepared for a new biological attack.

It is also worth noting that both the Secretary of Health and Human Services and the Secretary of Homeland Security currently have the authority to provide for Federal indemnity to private entities engaging in research, development, and production of biomedical countermeasures under Public Law 85-804. However, use of such authority is extremely rare. Also, in March 2003, President Bush revised Executive Order 10,789 governing use of the authority to provide for indemnity under Public Law 85-804 in the context of anti-terrorism technologies such as those to be developed under Project Bioshield. While HHS has been proactive in recognizing the need to consider use of the SAFETY Act, it must ensure that Federal indemnity remains available, where appropriate, as was the intention of both the law and the Executive Order.

Finally, while HHS is currently using its authority under Public Law 85-804 in very limited circumstances, it is our best understanding that the agency is not providing such indemnification/liability protection until a contact is awarded – and will not guarantee that this protection is forthcoming as part of the award process. This is not the intention of the law nor is it the practice of other agencies that have the authority to provide such liability protection to contractors. Congress should ensure, through Project Bioshield II, that HHS applies this provision in a way that was intended by both the law and regulations implementing Public Law 85-804.

Moreover, this issue places a potential contractor in the untenable position of having to perform "bare" and assume an unusually high legal risk, or refuse to perform, and be found in breach. Once a contract is awarded, a contractor has no meaningful negotiating strength, and is reliant on the contracting agency. In essence, we are reallocating labor, capital and resources and investing in high-risk products without sufficient assurance that liability protection will be available. It is essential that we fully address this situation.

Bioshield should provide for express authority to enter into agreements that resemble fully negotiated commercial transaction

Aventis Pasteur recommends that Project Bioshield be amended to expressly permit the Secretary of HHS to enter into "other transactions" in order to provide the maximum degree of flexibility suggested by the proposed legislation. "Other transaction" authority will permit agreements between HHS and industry that more closely resemble a fully negotiated commercial transaction. Similar authority has been provided to both the Department of Defense and NASA and has resulted in numerous success stories including, most recently, the "Predator" program in use in Afghanistan and Iraq today.

While HHS received "other transaction" authority, generally, for anti-terrorism activities under Title XVI of the Defense Authorization Act of 2004, HHS has taken no steps to implement use of this authority inside or outside the context of Project Bioshield. Moreover, under this legislation, HHS is required to receive permission from the Director of the Office of Management Budget before entering into such an agreement. Providing HHS with explicit authority to enter into "other transactions" without additional approval would allow HHS to maximize private sector participation in ensuring bio-defense measures are deployed and developed as broadly and quickly as possible.

Mr. Chairman, thank you for the opportunity to testify on this tremendously important issue. Aventis Pasteur has been and remains committed to contributing to our nation's common defense. I will be pleased to respond to any questions from members of the Committee.